



PATENT  
Attorney Docket No.: STK-010C3  
(7557/18)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Oppermann *et al.*  
SERIAL NO.: 10/671,317 GROUP NO.: Not yet assigned  
FILING DATE: September 25, 2003 EXAMINER: Not yet assigned  
TITLE: OSTEOGENIC DEVICES

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, which have been submitted for the parent cases from which this continuation application depends (U.S. Serial No. 09/956,582, filed on September 19, 2001, which is a continuation of U.S. Serial No. 09/074,299, filed on May 7, 1998; which is a continuation of U.S.S.N. 08/417,071, filed April 4, 1995, now U.S. Patent No. 5,814,604, issued on September 29, 1998, which is a continuation of U.S.S.N. 08/145,812, filed November 1, 1993, now U.S. Patent No. 5,750,651, issued on May 12, 1998; which is a divisional of U.S.S.N. 07/995,345, filed December 22, 1992, now U.S. Patent No. 5,258,494, issued November 2, 1993; which is a divisional of U.S.S.N. 07/315,342, filed February 23, 1989, now U.S. Patent No. 5,011,691, issued April 30, 1991; which is a continuation-in-part of U.S.S.N. 07/232,630, filed August 15, 1988, now abandoned; which is a continuation-in-part of U.S.S.N. 07/179,406, filed April 8, 1988, now U.S. Patent No. 4,968,590, issued November 6, 1990.) In accordance with 37 C.F.R. 1.98(d) copies of the patents and publications are not enclosed but are available upon request.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an

international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or

- ☐ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☐ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or
- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

#### STATEMENT

As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that [check the appropriate space only if either (2) or (3) is checked on the previous page and the Statement is required]:

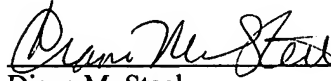
- ☐ 1. Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or
- ☐ 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any individual** designated in 37 C.F.R. 1.56(c) **more than three months** prior to the filing of the Information Disclosure Statement.

Date: November 14, 2003  
Reg. No.: 43,153

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Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Diana M. Steel", is written over a horizontal line.

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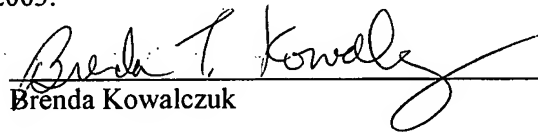
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TITLE: OSTEOGENIC DEVICES

**CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8**

I hereby certify that this correspondence, and any documents referred to as enclosed herein, are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 14<sup>th</sup> day of November, 2003.

  
Brenda Kowalczyk

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith are:

Transmittal (1 pg.); Information Disclosure Statement (3 pgs.); Form PTO-1449 (6 pgs.); this Certificate of First Class Mailing; and Return Receipt Postcard.

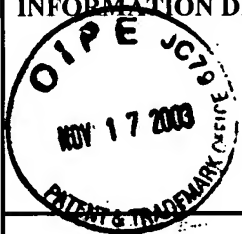


FORM PTO - 1449	ATTY DOCKET NO.: STK-010C3
INFORMATION DISCLOSURE STATEMENT	APPLICANT: Oppermann <i>et al.</i>
	SERIAL NO.: 10/671,317
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## U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A1	6,551,995	04/03	Oppermann <i>et al.</i>			
	A2	6,504,079	01/03	Tucker <i>et al.</i>			
	A3	6,468,308	10/02	Kuberasampath <i>et al.</i>			
	A4	6,461,630	10/02	Tucker <i>et al.</i>			
	A5	6,426,332	07/02	Rueger <i>et al.</i>			
	A6	6,333,312	12/01	Kuberasampath <i>et al.</i>			
	A7	6,297,213	10/01	Oppermann <i>et al.</i>			
	A8	6,281,195	08/01	Rueger <i>et al.</i>			
	A9	6,211,146	04/01	Kuberasampath <i>et al.</i>			
	A10	6,153,583	11/00	Oppermann <i>et al.</i>			
	A11	6,110,482	04/30/91	Khoury <i>et al.</i>			
	A12	6,077,988	06/20/00	Kuberasampath <i>et al.</i>			
	A13	6,013,856	01/11/00	Tucker <i>et al.</i>			
	A14	5,958,441	09/28/99	Oppermann <i>et al.</i>			
	A15	5,863,758	01/99	Oppermann <i>et al.</i>			
	A16	5,814,604	09/98	Oppermann <i>et al.</i>			
	A17	5,750,651	05/98	Oppermann <i>et al.</i>			
	A18	5,674,292	10/07/97	Tucker <i>et al.</i>			
	A19	5,652,337	07/97	Oppermann <i>et al.</i>			
	A20	5,496,552	03/05/96	Kuberasampath <i>et al.</i>			
	A21	5,354,557	10/11/94	Oppermann <i>et al.</i>			
	A22	5,344,654	09/06/94	Rueger <i>et al.</i>			

EXAMINER	DATE CONSIDERED
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<b>FORM PTO - 1449</b>  <b>INFORMATION DISCLOSURE STATEMENT</b>				<b>ATTY DOCKET NO.: STK-010C3</b>  <b>APPLICANT:</b> Oppermann <i>et al.</i>  <b>SERIAL NO.:</b> 10/671,317  <b>FILING DATE:</b> September 25, 2003  <b>GROUP:</b> Not yet assigned			
 <b>U.S. PATENT DOCUMENTS</b>							
EXAM. INIT.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE	
	A23	5,324,819	06/94	Oppermann et al.			
	A24	5,266,683	11/93	Oppermann et al.			
	A25	5,258,494	11/93	Oppermann et al.			
	A26	5,011,691	04/30/91	Oppermann et al.			
	A27	5,108,753	04/28/92	Kuberasampath et al.			
	A28	5,162,114	11/10/92	Kuberasampath et al.			
	A29	5,171,574	12/15/92	Kuberasampath et al.			
	A30	5,187,076	2/93	Wozney et al.	435	69.1	
	A31	5,166,058	11/92	Wang et al.	435	69.1	
	A32	5,154,931	10/92	Kruger et al.	424	549	
	A33	5,141,905	8/92	Rosen et al.	435	69.1	
	A34	5,116,738	5/92	Wang et al.	435	69.1	
	A35	5,108,922	4/92	Wang et al.	435	240	
	A36	5,106,748	4/92	Wozney et al.	435	252.3	
	A37	5,106,626	4/92	Parsons et al.	424	423	
	A38	5,013,649	5/91	Wang et al.	435	69.1	
	A39	4,877,864	10/89	Wang et al.	530	324	
	A40	4,843,063	6/89	Seyedin et al.	514	2	
	A41	4,810,691	3/89	Seyedin et al.	514	2	
	A42	4,804,744	2/89	Sen	530	350	
	A43	4,774,322	9/88	Seyedin et al.	530	353	
	A44	4,563,489	10/86	Urist	524	21	
	A45	4,563,350	1/86	Nathan et al.	424	95	
<b>EXAMINER</b>				<b>DATE CONSIDERED</b>			



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**U.S. PATENT DOCUMENTS**

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A46	4,455,256	6/84	Urist	530	350	
	A47	4,434,094	2/84	Seyedin et al.	530	416	
	A48	4,394,370	7/83	Jefferies	424	15	
	A49	4,294,753	10/81	Urist	530	395	
	A50	4,120,730	10/17/98	Trojer et al.			
	A51	2001/0016646	08/01	Rueger et al.			
	A52	2002/015985	10/02	Kuberasampath et al.			
	A53	2003/0032586	02/03	Rueger et al.			
	A54	2003/0064090	04/03	Khoury et al.			
	A55	2003/0069401	04/03	Oppermann et al.			

**FOREIGN PATENT DOCUMENTS**

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG Y/N
	B1	9300049	1/93	PCT					
	B2	9102744	3/91	PCT					
	B3	9011366	10/90	PCT					
	B4	9003733	4/90	PCT					
	B5	8910409	11/89	PCT					
	B6	8909605	10/89	PCT					
	B7	8800205	1/88	PCT					
	B8	8600526	1/86	PCT					
	B9	8505274	12/85	PCT					
	B10	0212474	4/87	EPO					

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## FOREIGN PATENT DOCUMENTS

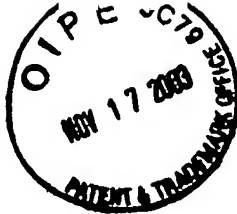
EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG Y/N
	B11	0182483	5/86	EPO					
	B12	0169016	1/86	EPO					
	B13	0148155	2/85	EPO					
	B14	0128041	12/84	EPO					

## OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)								
	C1	Canalis et al. (1980) Science 210: 1021-1023 "Stimulation of DNA and Collagen Synthesis by Autologous Growth Factor in Cultured Fetal Rat Calvaria."							
	C2	Glowacki et al. (1981) Lancet 1:959-963 "Application of the Biological Principle of Induced Osteogenesis for Craniofacial Defects."							
	C3	Reddi (1981) Collage Rel. Res. 1:209-226 "Cell Biology and Biochemistry of Endochondral Bone Development."							
	C4	Sampath et al. (1981) Proc. Natl. Acad. Sci. USA 78:7599-7603 "Dissociative Extraction and Reconstitution of Extracellular Matrix Components Involved in Local Bone Differentiation."							
	C5	Farley et al. (1982) Biochem. 21:3508-3513 "Human Skeletal Growth Factor: Characterization of Mitogenic Effect on Bone Cells In Vitro."							
	C6	Maugh (1982) Science 217:819 "Human Skeletal Growth Factor Isolated."							
	C7	Sampath et al. (1983) Proc. Natl. Acad. Sci. USA 80:6591-6595 "Homology of Bone-Inductive Proteins from Human, Monkey, Bovine, and Extracellular Matrix."							
	C8	Seyedin et al. (1983) J. Cell Biol. 97:1950-1953 "In Vitro Induction of Cartilage-Specific Macromolecules by a Bone Extract."							
	C9	Urist et al. (1983) Proc. Soc. Exp. Bio. Med. 173:194-199 "Human Bone Morphogenic Protein (hBMP)."							
	C10	Simpson (1984) Trends Biochem. Sci. 9:527-530 "Growth Factors Which Affect Bone."							
	C11	Urist et al. (1984) Clin. Orth. Rel. Res. 187:277-280 " $\beta$ -tricalcium Phosphate Delivery System for Bone Morphogenetic Protein."							

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<b>OTHER ART, JOURNAL ARTICLES, ETC.</b>			
<b>EXAM. INIT.</b>	<b>OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)</b>		
	<b>C12</b>	Urist et al. (1984) Proc. Natl. Acad. Sci. USA 81:371-375 "Purification of Bovine Bone Morphogenetic Protein by Hydroxyapatite Chromatography."	
	<b>C13</b>	Centrella (1985) Proc. Natl. Acad. Sci. USA 82:7335-7339 "Transforming and Nontransforming Growth Factors are Present in Medium Conditioned by Fetal Rat Calvariae."	
	<b>C14</b>	Klausner (1985) Biotechnology 3:567-568 "Collagen Corp. Isolates Cartilage Inducers."	
	<b>C15</b>	Olson et al. (1985) Analyt. Biochem. 146:232-257 "Deglycosylation of Chondroitin Sulfate Proteoglycan by Hydrogen Fluoride in Pyridine."	
	<b>C16</b>	Reddi (1985) J. Biomed. Materials Res. 19:233-239 "Implant-Stimulated Interface Reactions During Collagens Bone Matrix-Induced Bone Formation."	
	<b>C17</b>	Sampath & Reddi (1985) Extracellular Matrix: Structure and Function (A.H. Reddi, Ed., Allen R. Liss, Publ., NY pp. 412-428) "Role of Extracellular Matrix Components in Cartilage and Bone Induction."	
	<b>C18</b>	Seyedin et al. (1985) Proc. Natl. Acad. Sci. USA 82:2267-2271 "Purification and Characterization of Two Cartilage-Inducing Factors from Bovine Demineralized Bone."	
	<b>C19</b>	Urist et al. (1987) Methods in Enzymology 146:294-312 "Preparation and Bioassay of Bone Morphogenetic Protein and Polypeptide Fragments."	
	<b>C20</b>	Padgett et al. (1987) Nature 325:81-84 "A Transcript From A Drosophila Pattern Gene Predicts A Protein Homologous To The Transforming Growth Factor- $\beta$ Family."	
	<b>C21</b>	Sampath et al. (1987) Proc. Natl. Acad. Sci. USA 84:7109-7113 "Isolation of Osteogenin, An Extracellular Matrix-Associated, Bone-Inductive Protein, By Heparin Affinity Chromatography."	
	<b>C22</b>	Weeks et al. (1987) Cell 51:861-867 "A Maternal mRNA Localized to the Vegetal Hemisphere in Xenopus Eggs Codes For A Growth Factor Related to TGF- $\beta$ ."	
	<b>C23</b>	LeGendre et al. (1988) Biotechniques 6:154-159 "Direct Protein Microsequencing From Immobilon-P Transfer Membrane."	
	<b>C24</b>	Wang et al. (1988) Calcified Tissue Int. (Suppl.) Ab No. 146, pp. A37 "Purification and Characterization of Cartilage and Bone Inducing Factors."	
	<b>C25</b>	Wang et al. (1988) Proc. Natl. Acad. Sci. USA 85:9484-9488 "Purification and Characterization of other Distinct Bone-Inducing Factors."	

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
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SHEET 6 OF 6

<b>FORM PTO - 1449</b>		<b>ATTY DOCKET NO.: STK-010C3</b>	
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<b>EXAM. INIT.</b>	<b>OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)</b>		
	<b>C26</b>	Wozney et al. (1988) Calcified Tissue Int. (Suppl.) Ab No. 147 A37 "Identification Through Molecular Cloning of Factors Involved In Vivo Cartilage Formation."	
	<b>C27</b>	Wozney et al. (1988) Science 242:1528-1534 "Novel Regulators of Bone Formation: Molecular Clones & Activities."	
	<b>C28</b>	Lyons et al. (1989) Proc. Natl. Acad. Sci. USA 86:4554-4558 "Vgr-1, A Mammalian Gene Related To Xenopus Vg-1, Is a Member of the Transforming Growth Factor $\beta$ Gene Superfamily."	
	<b>C29</b>	Wang et al. (1990) Proc. Natl. Acad. Sci. USA 87:2220-2224 "Recombinant Human Bone Morphogenetic Protein Induces Bone Formation."	
	<b>C30</b>	Rueger et al. (1984) Calcified Tissue International 36: suppl. 2 pg. S69.	
	<b>C31</b>	Urist et al. (1983) Science, 220: 680-686.	
	<b>C32</b>	Ozkaynak (1990) EMBO J., 9: 2085-2093.	
	<b>C33</b>	Sampath (1990) J. Biol. Chem. 265: 13198-13205.	
	<b>C34</b>	Celeste (1990) Proc. Natl. Acad. Sci. USA 87:9843-9847.	

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